



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/710,239	11/10/2000	Robert C Chang	FG0219 US	4907

7590 11/14/2002
Leanne C Price Esq
FibroGen Inc
225 Gateway Blvd
South San Francisco, CA 94080

EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
----------	--------------

1653

DATE MAILED: 11/14/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/710,239

Applicant(s)

CHANG ET AL.

Examiner

Chih-Min Kam

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 August 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-21, 30, 42-51, 53-62 and 64-75 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2-6, 8, 9, 12-21, 30, 42-51, 53-62, 64-68 and 70-75 is/are allowed.
- 6) ☒ Claim(s) 7, 10, 11 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 6) ☐ Other: _____.

Art Unit: 1653

DETAILED ACTION

1. Claims 2-21, 30, 42-51, 53-62 and 64-75 are pending.

Applicants' amendment filed August 21, 2002 (Paper No. 13) is acknowledged, and applicant's response has been fully considered. Claims 2, 3, 5-14, 16-21, 30, 53-62 and 64-74 have been amended, claims 1, 22-29, 31-41, 52 and 63 have been cancelled, and a new claim 75 has been added.

Oath/Declaration

2. The newly submitted declaration filed August 21, 2002 (Paper No. 14) is acknowledged.

Objection Withdrawn

3. The previous objection of claims 4, 8, 12, 16-20 and 53 because of the misspelled word and being dependent upon a rejected base claim, is withdrawn in view of applicants' amendment to the claim and applicants' response at page 16 in Paper No. 13.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

4. The previous rejection of claims 14, 21, 30, 63 and 70 under 35 USC § 112, second paragraph, regarding the claim containing non-elected sequences, and the term "is derived from", "device", "a subject" or "fully-hydroxylated", is withdrawn in view of applicants' amendment to the claim, applicants' cancellation of the claim, and applicants' response at pages 18-19 in Paper No. 22.

Claim Rejections - 35 USC § 102

5. The previous rejection of claims 1, 5, 6, 42-52, 54-57, 61, 62, 64-68 and 71-74 under 35 USC § 102(b), as being anticipated by Pilliero *et al.* (U. S. Patent 5,330,773), Grossman *et al.*

Art Unit: 1653

(U. S. Patent 5,194,282), Russell *et al.* (U. S. Patent 5,827,852), Mason *et al.* (U. S. Patent 5,565,227), Todd (U. S. Patent 4,356,202), Bolinger (U. S. Patent 3,578,492), Zviak *et al.* (U. S. Patent 3,840,338), Helmstetter (U. S. Patent 4,055,554), McAleer *et al.* (U. S. Patent 4,147,772), Beyer *et al.* (Br. J. Anesthesia 78, 44-50 (1997)), Di Silvio *et al.* (J. Mater. Sci.: Mater. Med. 5, 819-823 (1994)) or Kanatani *et al.* (Agri. Biol. Chem. 53, 1185-1187 (1989)), is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 19-25 in Paper No. 13.

6. The previous rejection of claims 1-3, 9, 11, 13-15 and 58-60 under 35 USC § 102(a), as being anticipated by Werten *et al.* (Yeast 15, 1087-1096 (August, 1999)), Luks *et al.* (Am. J. Obstet. Gynecol. 181, 995-996 (October, 1999)) or Mligiliche *et al.* (East African Med. J. 400-406 (July, 1999)), is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 19-25 in Paper No. 13.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 7, 10, 11 and 69 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 7 and 69 are indefinite because of the use of the term "partially hydroxylated". The term "partially hydroxylated" renders the claim indefinite, it is unclear to what extent the recombinant gelatin is hydroxylated as to "partially hydroxylated".

Art Unit: 1653

In response, applicants indicate the specification discloses the present invention comprises fully hydroxylated, partially-hydroxylated and non-hydroxylated, and recombinant gelatins ranging from non-hydroxylated to fully-hydroxylated (page 34, lines 21-22, and page 26, lines 17-18), thus, a person of skill in the art would understand the term in view of the specification (page 17 of the response). The argument is not found persuasive because the specific degree of hydroxylation such as 20-80% is indicated in the specification (page 34, lines 21-27), but is not cited in the claim, e.g., the specification does not indicate the gelatin has less than 20% hydroxylation. Claim 69 is included in the rejection because it is dependent on a rejected claim and does not correct the deficiency of the claim from which it depends.

6. Claim 10 is indefinite because of the use of the term “is hydrolyzed”. The term “is hydrolyzed” renders the claim indefinite, it is unclear what products are obtained after hydrolysis, and whether the hydrolyzed gelatin has the properties of gelatin.

7. Claim 11 is indefinite because of the use of the term “partially hydrolyzed”. The term “partially hydrolyzed” renders the claim indefinite, it is unclear to what extent the recombinant gelatin is hydrolyzed as to “partially hydrolyzed”, and whether the partially hydrolyzed gelatin has the properties of gelatin.

In response, applicants indicate the term is widely used and understood in the art, and a person of skill in the art would understand the term in view of the specification (page 18 of the response). The argument is not found persuasive because the claim does not recite the extent of the hydrolysis of the gelatin, nor indicates the condition of the hydrolysis, thus, it is not clear what gelatin product is obtained after partial hydrolysis, and whether the partially hydrolyzed gelatin has the properties of gelatin.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

8. Claim 7 is rejected under 35 U.S.C. 102(e) as being anticipated by Olson *et al.* (US 6,413,742, priority date May 8, 1998).

Olson *et al.* teach the production of recombinant gelatin using constructs encoding any collagen monomer, preferably lacking the C propeptide domain and/or the N propeptide domain in a recombinant host cell, and the collagen monomers produced may be hydroxylated, e.g., in a cell with prolyl-4-hydroxylase activity. After collection and purification, the collagen monomers are denatured to form gelatin (column 4, lines 24-35; column 6, lines 18-23; column 8, lines 3-17; claim 7).

Art Unit: 1653

Conclusion

9. Claims 7, 10, 11 and 69 are rejected, and it appears claims 2-6, 8, 9, 12-21, 30, 42-51, 53-62, 64-68 and 70-75 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

Karen Cochrane Carlson
KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

November 9, 2002